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EXAMINER	
WHALEY, PABLO S	
ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
11/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/687,636	RAMBAUD, PATRICK	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,34 and 36-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,34 and 36-55* is/are rejected.

7)☒ Claim(s) *52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/16/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Request For Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/29/2010 has been entered.

Withdrawn Rejections/Objections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn in view of the amendments filed 07/29/2010. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Number of Claims

Claim 52 is missing from the set of claims filed 07/29/2010. Therefore claims 53, 54, and 55 have been renumbered as claims 52, 53, and 54, respectively, under 37 CFR 1.126.

Status of the Claims

Claims 33, 34, and 36-54 are pending and under consideration.

Claims 1-32 and 35 are cancelled.

Information Disclosure Statement

The information disclosure statement filed 09/16/2010 has been considered in full.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 34, and 36-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

This is a NEW MATTER rejection.

Amended claims 33 and 36 recite "determining parameters..., using data stored in said database, said determined parameters including optimized proportions...for better tolerance...and greater reaction speed, using the subject's immunity data stored in the database". No basis has been pointed to for these new limitations. The specification states "When a re-use process of immunocompetent cells is prescribed for a human or animal subject, a protocol of deferred-use is determined using data stored in the database with, for example, optimal proportions between each type of cells. Selected immunocompetent cells are then extracted from the personal cell library and, if necessary, processed ex-vivo (See at least pages 6 and 15). There is no disclosure that

relates determining parameters that include "optimized proportions" or determining optimized parameters using "immunity data". In the absence of support, these claims and claims dependent thereon are deemed to constitute new matter.

Newly added claim 45 recites "wherein the autologous vaccine is a flu vaccine with cytotoxic activity." No basis has been pointed to for these new limitations and no support has been found in the specification. In the absence of support, these claims and claims dependent thereon are deemed to constitute new matter.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 34, and 36-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claims 33 and 36 are also rejected due to said dependence.

Claim 33 recites a status-characterizing information device comprising an expert system and "implementing into said expert system a process for determining a deferred use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells…from said subject" (see lines 30-35), which appears to be a method step. However, as the claimed invention is directed

to a device, recitation of an apparent method step renders the claim confusing. It is unclear whether applicant intends this limitation to be a further limitation of said device, and if so, what structural limitation is intended. For example, what device implements data into said expert system?

Claims 33 and 36 recite "determining parameters..., using data stored in said database, said determined parameters including optimized proportions...for better tolerance...and greater reaction speed, using the subject's immunity data stored in the database" (see last 8 lines of the claims). The use of two separate "using" phrases makes it unclear what data is used for determining parameters. For example, one interpretation of the claims as written is that parameters are determining using ANY of the data stored in said database. However, a second interpretation of the claims as written is that parameters are determining specifically using the immunity data stored in the database. Which is it?

Claim 34 recites "The device according to claim 33." There is insufficient antecedent basis for this limitation. Claim 33 is directed to a system. This rejection could be overcome, for example, by replacing "device" with "system." Correction is requested.

Claim 44 recites "The method according to claim 36 prepare an autologous vaccine." It is unclear what limitation of the method is intended. This rejection could be overcome by replacing "prepare" with "further comprising preparing."

Claim 41 recites "before, any re-use of a batch of immunocompetent cells previously collected, a step for checking the annihilation of the antibodies within said batch." (1) There is insufficient antecedent basis for "the annihilation." There is no

previous step for performing an "annihilation" in the parent claims. (2) There is insufficient antecedent basis for "the antibodies." There is no previous recitation of antibodies in any of the parent claims. This rejection could be overcome, for example, by amending the claim to recite a previous step for "annihilating antibodies in the batches of immunocompetent cells before any re-use of a batch."

Claim 47 recites "checking the antibodies to be annihilated in order not to harm the receiver prior to injection." (1) There is insufficient antecedent basis for "the antibodies." There is no previous recitation of antibodies in any of the parent claims. (2) It is unclear what positive limitation of the claim is intended due to the use of future tense language (e.g. "to be annihilated"). For example, is this simply an intended use of the antibodies or does this claim require a step of annihilation of antibodies or is? This rejection could be overcome, for example, by amending the claim to recite "checking antibodies in the batches of immunocompetent cells prior to injection and annihilating those that would harm the receiver."

NEW GROUND OF REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33, 36, 37, 38, 39, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Winkel (Clinical Chemistry, 1989, 35/8, p.1595-1600), and in view of Adrion et al. (US 5,023,785; Issue Jun. 11, 1991; IDS filed 09/16/2010).

The instant claims are drawn to a system and method for managing batches of immunocompetent cells collected from human or animal subjects for their deferred use.

For purposes of examination, the components of the system include a storage device, collection device, status-characterizing device to determine identity data comprising expert system that uses biological items and applies a set of rules stored in a knowledge base, a cell management processor for storing identity data, an identification device for performing identification of batches, and a processor for processing successively collected subject identity data. For purposes of examination, critical limitations of the claimed method are interpreted as follows: collecting plural collecting immunocompetent cells for successive collection stages, storing the collected cells, creating a personal cell library from successively collected cells and personal database comprising status characterization data and subject identity data, generating subject-s identity data using an expert system, determining a deferred-use protocol comprising biological and technical indications, determining parameters for said deferred-use protocol including optimal proportions of various selected types of cells for better tolerance by said patient and greater reaction speed, extracting selected immunocompetent cells from said personal library, and processing said extracted immunocompetent cells according to said deferred-use protocol. It is noted that "deferred use protocols" has not been defined in the specification and is broadly interpreted as a medical treatment recommendation.

Lefesvre teaches batch management system for managing immunocompetent lymphocyte cells obtained from human subjects [p. 1, ¶1]. In particular, Lefesvre teaches one or more cryogenic storage sites wherein each batch of immunocompetent cells are collected, stored, and preserved for deferred use [p.2, ¶7, ¶8, p. 3]. The

information collected for processing includes personal data relating to the subject, cellular identification data, immunity related information, and gene therapy protocol information [p.2, ¶8, p.2, ¶ 12, Fig. 1, p.3, p.4, ¶5]. Lefesvre teaches processing of blood to collect information indicative of patient health status [p. 1 and Fig. 1, p.3, ¶ 9], which shows a status characterization step of collecting information. A plurality of cellular processing centers are described for batch processing of immunoqualified cells [p.3, ¶1]. The centers provides means for communicating with storage sites, producing a personal library of immunoqualified lymphocyte cells, which inherently store immunity information, and identifying stored batches of cells in response to requests for treatments using said cells [p.3, ¶1, See also p.2, ¶ 2, p.4, ¶ 4]. Lefesvre provides a database that can be queried by a user to obtain information [p.3, last ¶]. Lefesvre teaches protocols for performing identification of cells and consulting a cell management database system[p.3, ¶1-¶3, p.4, ¶1], receiving requests for subject identity data [p.3, last ¶], and processing of the database based on patient specific requests [p.4, last ¶, p.4]. Lefesvre shows a process for selecting and removing cells from a personal library according to deferred use protocols and components for re-using lymphocytes in the patient [p.4, ¶ 2, and p.4, ¶7 onwards], which shows selecting cells for extraction. Lefesvre describes steps for gathering personal data for processing before re-use [p.4, ¶2, ¶5]. The system makes possible the batch storage of cells in accessible and identifiable form for deferred use protocols including gene therapy protocols, restoring cellular immunity, gene therapy, genetic analysis, infection detection, etc. [p.2, ¶6, p.2, ¶ 12, p.4, ¶8, p. 3]. The overall management process

includes storage centers that are controlled using software [p.3, ¶1, See also p.2, ¶ 2, p.4, ¶ 4]. Lefesvre also describes a re-use process for defrosting an aliquot (i.e. proportion) of selected immunocompetent cells from storage, treating them using specific treatment agents (i.e. optimization), and re-injecting them into a patient for deferred use [p.2, ¶6], and additionally describes selecting appropriate cells using information from a database [p.3, last two ¶].

Lefesvre does not teach an expert system that uses biological items and applies a set of rules stored in a knowledge base, as in claims 33 and 36.

Lefesvre does not teach an expert system that determines a deferred use protocol comprising biological and technical indications required for cell processing, as in claims 33 and 36.

Lefesvre does not teach a processor for determining parameters including optimized proportions of various selected cell types from the personal cell library using the subject's immunity data, as in claims 33 and 36.

Winkel teaches expert systems applied to clinical laboratory data. In particular, the described expert systems use rules for producing diagnostic results and treatment recommendations (i.e. deferred use protocols); see p.1596, and p.1597, Col. 1. Such systems can be configured to use various programs using various types of laboratory data stored in databases; see Figure 1 and Table 1.

Adrion teaches an expert system comprising a computer/data processor for outputting diagnostic information of a patient. In particular, the expert system includes functionality for determining clinically important combinations of blood-derived

parameters (i.e. optimizing parameters) using hematology data stored in a database; see Ref. claim 1. Additionally, the parameters can include a plurality of different types of cells including lymphocyte/monocyte ratio amounts; see Ref. claims 1 and 4, which is interpreted as portions of cells.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used an expert system that uses biological items and applies a set of rules stored in a knowledge base, as taught by Winkel, in the system and method of Lefesvre, with a reasonable expectation of success, since Lefesvre suggests using biological information and deferred use protocols with a processing system [p.2, ¶6, ¶8]. The motivation would have been to improve treatment recommendations with an automated consultation system, as suggested by Winkel [p.1595, Col. 1].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used an expert system that determines a deferred-use protocol, as taught by Winkel, using biological data in the system and method made obvious by Lefesvre and Winkel, with a reasonable expectation of success, since Lefesvre suggests using biological information and deferred use protocols with a processing system [p.2, ¶6, ¶8]. The motivation would have been to improve treatment recommendations with an automated consultation system, as suggested by Winkel [p.1595, Col. 1].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have configured a processor for determining optimized proportions of various selected cell types using the subject's immunity data, in the system and

method made obvious by Lefesvre and Winkel, with a reasonable expectation of success, since Adrion determines clinically important combinations of blood-derived parameters using hematology data, wherein the data can include portions of cell types, as set forth above, which reasonably suggests selecting optimized portions of cells using subject immunity data. The motivation would have been to improve treatment by only using clinically significant aliquots (i.e. portions) of selected cells for deferred use, as suggested by Lefesvre [p.2, ¶6,, and p.3, last two ¶].

Claims 34 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Winkel (Clinical Chemistry, 1989, 35/8, p.1595-1600), and in view of Adrion et al. (US 5,023,785; Issue Jun. 11, 1991; IDS filed 09/16/2010), as applied to claims 33, 36, 37, 38, 39, and 43, above, and further in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997), and in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137).

Lefesvre, Winkel, and Adrion make obvious a method and system for managing batches of immunocompetent cells for deferred use, as set forth above.

Lefesvre, Winkel, and Adrion do not teach a device for collecting bioelectronic information resulting from processing measures as in claims 34 and 40.

Zanin teaches a method and device for measuring, processing, and storing bio-electrical signals [Abstract, p.2, Fig. 1, p.6]. Collected and processed information

includes parameters and data relating to various measured levels including pH [p.9, last ¶]. In addition, Zanin also teaches an expert system comprising control and interpretation software to provide the physician with tools for determining patient health status and reliable treatments [Abstract, p.3, Ref. claims 3 and 5].

Cha teaches a routine method for obtaining bioelectronic information by processing previously collected patient blood samples. The information includes resistance (i.e. resistivity) and reactance data [Abstract, Fig. 1, Section 3].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have provided a predictable variation of the type of data and devices used, such as bioelectronic data and devices, in the system and method made obvious by Lefesvre, Winkel, and Adrion, with a reasonable expectation of success, in view of the prior art of Zanin and Cha, who perform processing bioelectronic data using expert systems, and in view of the rationale for a *prima facie* case of obviousness provided by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). See MPEP 2143. In this case, the rationale would have been to explore methods for improving patient care based on variations of known design incentives, such as bioelectronic data and related devices commonly used in patient health assessment, as suggested by Zanin [p.1, ¶3] and Cha et al. [p.136, ¶ 3and 4], since these variations are predictable to one of ordinary skill in the art. For these reasons, the instant claims do not recite any new element or new function or unpredictable result.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Winkel (Clinical Chemistry, 1989, 35/8, p.1595-1600), in view of Adrion et al. (US 5,023,785; Issue Jun. 11, 1991; IDS filed 09/16/2010), in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997), and in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137), as applied to claims 33, 34, 36, 37, 38, 39, 40, and 43, above, and further in view of Tomoyasu (Applied And Environmental Microbiology, Jan. 1998, p. 376–382).

Lefesvre, Winkel, Adrion, Zanin, and Cha make obvious a method and system for managing batches of immunocompetent cells for deferred use, as set forth above.

Lefesvre, Winkel, Adrion, Zanin, and Cha do not teach a step for immunomagnetically selecting purified lymphocytes or monocytes, as in claim 42.

Tomoyasu teaches a method for immuno-magnetically separating cells using Dynabeads [Abstract].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have provided a predictable variation of the type of process used for separating cells, such as using immunomagnetics, in the system and method made obvious by Lefesvre, Winkel, Adrion, Zanin, and Cha, with a reasonable expectation of success, in view Tomoyasu who shows conventional methods of immunomagnetic separation of cells, as set forth above, and in view of the rationale for a *prima facie* case of obviousness provided by the Supreme Court in *KSR International Co. v. Teleflex Inc.*,

550 U.S. 398 (2007). See MPEP 2143. In this case, the rationale would have been to explore methods for separating cells based on variations of known design incentives, such as using improved immunomagnetic techniques, as shown by Tomoyasu, since these variations are predictable to one of ordinary skill in the art. For these reasons, the instant claims do not recite any new element or new function or unpredictable result.

Claims 41 and 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Winkel (Clinical Chemistry, 1989, 35/8, p.1595-1600), in view of Adrion et al. (US 5,023,785; Issue Jun. 11, 1991; IDS filed 09/16/2010), in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997), and in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137), in view of Tomoyasu (Applied And Environmental Microbiology, Jan. 1998, p. 376–382), as applied to claims 33, 34, 36, 37, 38, 39, 40- 43, above, and further in view of Privitera et al. (US 4,826,760; Issued: May 2, 1989) and Barocci et al. (Transpl. Int., 1993, 6:29-33)

Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu make obvious a system and method for managing batches of immunocompetent cells for deferred use, as set forth above. Lefesvre additionally teaches administering a vaccine to a patient via lymphatic injection [see p.2, ¶6], as in claim 46.

Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu do not teach annihilating antibodies within immunocompetent cells prior to re-use, as in claims 41 and 47.

Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu do not teach preparing an autologous vaccine using specific parameters of T4/T8 ratio, as in claims 44 and 48-54.

Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu do not teach preparing a flu vaccine with cytotoxic activity, as in claim 45.

Barocci teaches methods for removing antibodies from sera [Abstract].

Privitera teaches methods for determining specific T4/T8 lymphocyte ratios for treating patients [see at least Col.1 and Col. 2], which is interpreted as an autologous vaccine. Supressor/cytotoxic T cells bear the T8 antigen [Col. 2, ¶2], which shows cells with cytotoxic activity. Such ratios can assist in the treatment of a wide variety of disorders [Col. 2].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have removed antibodies from cells prior to injection, in the system and method made obvious by Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu, with a reasonable expectation of success, since Barocci shows that experimental techniques for removing harmful antibodies from sera would have been predictable to one of ordinary skill in the art. The motivation would have been to improve quality control by ensuring that future patients are not given injections containing infected cells, as suggested by Lefesvre [see at least p.2, and p.4, ¶ 2],

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have prepared specific parameters of a T4/T8 lymphocyte ratio, in the system and method made obvious by Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu, with a reasonable expectation of success, since Lefesvre teaches methods

for preparing and treating patients with lymphocytes, as set forth above, and since Privitera explicitly provides specific T4/T8 lymphocyte ratios for treatment, as set forth above. The motivation would have been to assist in the treatment of a wide variety of disorders, as suggested by Privitera [Col. 2].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have prepared a vaccine with cytotoxic activity, in the system and method made obvious by Lefesvre, Winkel, Adrion, Zanin, Cha, and Tomoyasu, with a reasonable expectation of success, since Privitera shows that T cells have cytotoxic activity, as set forth above. The motivation would have been to assist in the treatment of a wide variety of disorders, as suggested by Privitera [Col. 2].

Response to Arguments

Applicant's arguments filed 7/29/2010 that Lefesvre, Shortliffe, and Barnhill do not teach determining parameters of a deferred-use protocol, wherein the said parameters include optimized proportions of various selected types of cells among cells stored in said personal cell library for better tolerance by said patient and a greater reaction speed, using the subject's immunity data stored in said database, using the subject's immunity data stored in said database", the claims do not set forth any specific steps for determining parameters by "using the subject's immunity data stored in said database" , have been fully considered and are persuasive. Therefore the rejections of claims_33, 34, and 36-42 under 35 U.S.C. 103(a) as being unpatentable over Lefesvre in view of Barnhill, Shortliffe, Zanin, Cha, and Tomoyasu are withdrawn. However, a

new ground of rejections has been applied in view of applicant's amendments, as set forth above.

Applicant's additional arguments directed to Shortliffe and Barnhill are moot for the reasons set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 12pm-8pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley
Patent Examiner
Art Unit 1631

/PW/

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631